

January 15, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

December 23, 1998

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401 M Street, SW
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SUBJECT: *Response to the Draft EFED Reregistration Eligibility Decision (RED)
Science Chapter for Azinphos-methyl, List A Case 0235*

Following is a response to the draft Environmental Fate and Effects Division (EFED) chapter for azinphos-methyl which BAYER received from the EPA on November 30, 1998. BAYER has already commented on the Health Effects Division (HED) chapter on 8/11/98 and 10/9/98.

BAYER reiterates that this chapter contains preliminary, screening-level calculations based on all "current" azinphos-methyl labels. It does not take into account any of the measures proposed by BAYER over the last several months to improve upon the existing record of safe use and to further refine the risk assessments. Some of those refinements include cancellation of some older formulations and uses for which significant alternatives exist. BAYER is somewhat disappointed that the tone of the EPA document is so negative, basing much of its conclusions on predictive models and misused incident data. Many conclusions are stated without any recommendations for potential exposure reduction or risk mitigation. BAYER has strived to work hard with the Agency and user community to maintain this important agricultural tool, and will continue that effort as the reregistration process continues.

BAYER has identified a number of errors which should be resolved before this document is made "final", so that an accurate assessment of environmental risk due to azinphos-methyl use can be clarified. Please consider the following:

Errors identified in the Environmental Fate discussions in the RED chapter:

1. This chapter states there are no submitted data on the aerobic aquatic metabolism of Guthion (p. 3, section 2.b.; and also on page 4 under "Data Gaps" in the memorandum to Barry O'Keefe). An aerobic aquatic study has been submitted, (MRID 44411801) but it appears that this report was not reviewed.
2. In Table 2, page 7, the half-life reported for MRID 42516702 is 0.53 days, not 2.56 days. This study was conducted in Georgia, not Mississippi. The foliar half-life measured in Mississippi was 1.17 days as reported in MIRD 425167-01. The results of both studies should be considered by the Agency as foliar half-life is important to ecotox issues.
3. In the last paragraph of page 10, field dissipation of Guthion in surface soil is described with the comment that no zero time samples were taken. In fact, the collection and analysis

of soil samples taken one day before and immediately following application (zero time) are detailed in these reports. As reported, the Mississippi site received only 0.16 inches of rainfall 22 days into the 28-day sampling period. Since a half-life of 5.7 days was calculated from the data, the correct interpretation is that the rainfall did not confound the degradation rate in this study by allowing for leaching. Chemical movement with water was also not a factor in the soil dissipation component of the Georgia study since the first significant rainfall occurred 19 days following application where the half-life was only 6.4 days.

4. The Agency utilized a single monitoring study to establish an acute ground water exposure of 75 ppb (as reported in Table 6, page 14). The study by Goodell which the Agency uses to support this exposure has a very high level of uncertainty. This report was not peer-reviewed and contains no details of performance for a multi-residue method described only as using filtered water for extraction and analysis by gas chromatography using an electron capture detector. In addition, the report does not provide the observed concentrations of pesticides investigated. Only "occurrences" are reported with general references to concentrations observed. The comment made on page 31: *"This data set has some significant uncertainties associated with it."* should be sufficient to demonstrate that this report should not be the basis of the Agency's acute exposure estimate for ground water.
5. In the surface water assessment (EXAMS), a value of $1.02 \times 10^{-4} \text{ h}^{-1}$ was used for the aerobic aquatic degradation rate (see Table 22), but it is not specified how this value was derived. This value is equivalent to a half-life of 283 days, which is significantly slower than even the hydrolysis rate in sterile pH-4 water whereby Guthion is most stable ($t_{1/2} = 87$ days). This error has a significant effect on the results of the surface water assessment.

Ecotoxicology errors in the Guthion EFED RED

1. On page 33, table 26, the NOEC for the Bobwhite reproduction study is reported as 15.6 ppm. This value is incorrect. The correct value is 36.5 ppm, which is consistent with the reported LOEC of 87.4 ppm.
2. On page 34, table 28, the Deer Mouse (MRID No. 408583-01) study is reported as being supplemental due to the fact that dietary concentrations were not confirmed. This information was provided to the agency in June of 1989 (MRID No. 41367201).
3. Terrestrial field and pen tests (pages 36 - 38). It is incorrect to use the term "suspect" in the third column of table 32 when the authors of the study classified them as possible. Not including a column in table 32 of the casualties found that were not treatment related is an error of omission. Any objective discussion of the Washington study would include a reference to the fact that, unknown to the researchers at the time, a rodenticide was used in two of the 8 replicate sites. A disproportionate number of casualties, 55% of all casualties and 67% of all mammalian casualties, were found in these two replicates. The number of

casualties found on the 2 replicates treated with both Guthion and rodenticide averaged 3.7 times greater than in the 6 replicates where only Guthion was used.

Not included in review of field studies is the study referenced below conducted by Environment Canada which concluded that there was no evidence that use of azinphos-methyl in apple orchards or on potato fields caused an effect on birds at the population or community level.

“Graham, D.J. and J. DesGranges. 1993. Effects of the organophosphate azinphos-methyl on birds of potato fields and apple orchards in Quebec, Canada. *Agriculture, Ecosystems and Environment* 43:183-199.

4. Table 3, page 39 - List of tests conducted with fish is missing the GLP study listed below with Rainbow trout that the registrant has submitted. The 96-h LC50 from this study was 3.0 ug/L.

“Carlisle, J.C. 1984. Acute toxicity of azinphos-methyl (Guthion) Technical to rainbow trout. Bayer Report No. 86642, MRID No. 158231”

5. Page 43 - the phrase .. "The lowest endpoint was 1.2 ug ai/L on the **brown trout**." Should say **brook trout**.
6. Bayer has submitted a mesocosm study (MRID No. 41549401) with Guthion which was not included in the listing of available aquatic toxicity studies.
7. Page 48, table 39 - For the studies with MRID Nos. 41202002 and 40380502, the table incorrectly lists the test species as *Americamysis bahia*. The species was referred to in the study reports as *Mysidopsis bahia* or the mysid shrimp. The species name used in the RED is inconsistent with the original reports and common taxonomic usage. Usage of *Americamysis bahia* or opossum shrimp should be corrected and changed to *Mysidopsis bahia* or the mysid shrimp through out the RED (pg 54, 79 - 83, etc.)
8. **The maximum EEC, Average Maximum EEC, and most of the Risk quotients (RQ) reported in Tables 43 - 58 for birds and mammals are in general missing or incorrect.** The only values that appear to be routinely correct in these tables are the values reported "Mean EEC" or equivalent columns. Some of the RQ values based on the Mean EEC also appear to be correct, but not all of them. For example on page 70, table 57 for the tomato crop grouping the Avg. Max. EEC and associated RQs are clearly incorrect, while the Avg. Mean EEC and associated RQs appear to be correct. For most of the other crop groupings in the table 70, a value of zero or "???" is given for the Avg. Max. EEC and both columns of RQ.

These widespread errors in the avian and mammalian EECs and RQs make it

impossible to judge whether the conclusions on the risk of azinphos-methyl to birds and mammals are supported by accurate and correct calculations.

9. In assessing the chronic risk to birds and mammals, the averaging period and techniques used to generate the average EECs is not given, so that the accuracy of the values can not be fully verified.
10. All references to "Bayer Inc.'s" in tables 59 to 89, and anywhere else in the document should be replaced with "Bayer Corporation's." Bayer Inc. would refer incorrectly to BAYER Canada operations.
11. The accuracy of table 90, on page 88 is impossible to judge due to the widespread errors in tables 43 -58, but it is clear that some of the values reported do not match the values in tables 43 - 58 and appear to be incorrect.
12. The table on pages 145 to 147, "Phase IV Data Requirements for Ecological Effects Branch" is not filled out.

The Agency has additionally requested a statement relative to the presence of Confidential Business Information (CBI) as described in FIFRA sections 10(d)(1)(A)-(C) in the RED chapter and our response. BAYER has examined the documents and found no information which could be classified as CBI as defined by FIFRA.

BAYER is more than willing to meet with the Agency in the coming months to discuss these errors as well as what additional information or studies are needed. Additionally, these meetings could discuss potential "next steps" relative to possible exposure reduction measures and how they might affect the risk assessment process.

In conclusion, as reiterated in previous communications, BAYER stands behind the safety of azinphos-methyl under current use conditions. We will continue to work with the Agency and User Community to address issues and concerns raised by the Agency or FQPA. If you have any questions, please contact either me or Dr. James Kunstman at (816) 242-2838.

BAYER CORPORATION

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cc: George Tompkins - EPA/Reg Div.